DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Clinical Laboratory Improvement Advisory Committee (CLIAC). This meeting is open to the public, limited only by the webcast lines available. Check the CLIAC website on the day of the meeting for the web conference link *www.cdc.gov/cliac*.

DATES: The meeting will be held on November 3, 2021, from 11:00 a.m. to 6:00 p.m., EDT, and November 4, 2021, from 11:00 a.m. to 6:00 p.m., EDT.

ADDRESSES: This is a virtual meeting. Meeting times are tentative and subject to change. The confirmed meeting times, agenda items, and meeting materials including instructions for accessing the live meeting broadcast will be available on the CLIAC website at *www.cdc.gov/cliac*.

FOR FURTHER INFORMATION CONTACT: Nancy Anderson, MMSc, MT(ASCP), Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory

Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop V24-3, Atlanta, Georgia 30329-4027, Telephone: (404) 498-2741; *NAnderson@cdc.gov*.

SUPPLEMENTARY INFORMATION:

PURPOSE: This Committee is charged with providing scientific and technical advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; the Director, CDC; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendments of 1988(CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

MATTERS TO BE CONSIDERED: The agenda will include agency updates from CDC, CMS, and FDA. In addition to the general updates, agency presentations will include an overview of the FDA's Center for Biologics Evaluation and Research, a laboratory safety update, and a status report on the new CLIA regulations assessment workgroup. Presentations and CLIAC discussion will focus on next generation sequencing in clinical and public health laboratories and laboratory data exchange and harmonization. Agenda items are subject to change as priorities dictate.

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments pertinent to agenda items. Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item. In general, each individual or group requesting to present an oral comment will be limited to a total time of five minutes (unless otherwise indicated). Speakers should email *CLIAC@cdc.gov* or notify the contact person at least five business days prior to the meeting date. For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least five business days prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. All written comments

will be included in the meeting Summary Report posted on the CLIAC website.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit,

Office of the Chief Operating Officer,

Centers for Disease Control and Prevention.

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